

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Previously Presented) A light-stabilized soft capsule formulation comprising:

a shell containing a non-water-soluble light-shielding agent and having an average thickness of 200 μm or less; and

a medicament encapsulated by said shell, wherein the amount of the non-water-soluble light-shielding agent is 5 to 30 wt%, based on the total amount of all components constituting the shell; and

wherein light transmittance of the shell is less than 0.6%.

Claim 2. (Cancelled).

3. (Previously Presented) The light-stabilized soft capsule formulation according to claim 1, wherein the non-water-soluble light-shielding agent is titanium oxide.

4. (Previously Presented) The light-stabilized soft capsule formulation according to claim 1, wherein the

soft capsule formulation has an average capsule size of 2 mm or less.

5. (Previously Presented) The light-stabilized soft capsule formulation according to claim 1, wherein the shell is seamless.

6. (Previously Presented) The light-stabilized soft capsule formulation according to claim 1, wherein the medicament is a light-unstable substance.

7. (Previously Presented) The light-stabilized soft capsule formulation according to claim 1, wherein the medicament is in a liquid form or the medicament is dissolved or suspended in a liquid base.

8. (Original) The light-stabilized soft capsule formulation according to claim 7, wherein the medicament is a vitamin D derivative.

9. (Previously Presented) The light-stabilized soft capsule formulation according to claim 1, wherein the major component of the shell is gelatin.

10. (Withdrawn) A method for preparing a shell-forming solution which is used to form a soft capsule shell containing a non-water-soluble light-shielding agent, said

method comprising the step of dispersing the non-water-soluble light-shielding agent in a medium free from a gelling agent.

11. (Withdrawn) A method for manufacturing a soft capsule formulation containing a non-water-soluble light-shielding agent in its shell, comprising:

(i) the step of preparing a shell-forming solution, comprising the following steps (a) to (c) :

(a) dissolving a gelling agent in Medium A;
(b) dispersing the non-water-soluble light-shielding agent in Medium B free from the gelling agent; and
(c) mixing Medium A containing the gelling agent dissolved therein with Medium B containing the non-water-soluble light-shielding agent dispersed therein; and

(ii) the step of forming a capsule shell for the soft capsule formulation using the shell-forming solution prepared in the step (i).

12. (Withdrawn) The method for manufacturing a soft capsule formulation according to claim 11, wherein the step of forming a capsule shell for the soft capsule formulation is accomplished by the in-liquid curing coating method.

13. (Withdrawn) The light-stabilized soft capsule formulation comprising:

a shell containing a non-water-soluble light shielding agent and having an average thickness of 200 m or less; and

a medicament encapsulated by said shell,
said shell being manufactured by the method according to claim 11, and

wherein the amount of the non-water soluble light-shielding agent is 5-30 wt% based on the total amount of all components constituting the shell.

14. (Previously Presented) A unit dose package comprising the light-stabilized soft capsule formulation according to claim 1.

15. (Previously Presented) A hard capsule, a tablet, an oral solution or an external preparation, which is prepared using the light-stabilized soft capsule formulation according to claim 1.

16. (Previously Presented) The light-stabilized soft capsule formulation of claim 1 wherein the amount of the non-water-soluble light-shielding agent is 10-25 wt%.

17. (Previously Presented) The light-stabilized soft capsule formulation of claim 1 wherein the amount of the non-water-soluble light-shielding agent is 15-20 wt%.

18. (New) The light-stabilized soft capsule formulation according to claim 1,

wherein the amount of non-water-soluble light-shielding agent is 5 to 25 wt%, based on the total amount of all components constituting the shell.

19. (New) The light-stabilized soft capsule formulation according to claim 1,

wherein the amount of the non-water-soluble light-shielding agent is 5 to 25 wt%, based on the total amount of all components constituting the shell; and

wherein the soft capsule formulation has an average capsule size of 2mm or less.